REMARKS

Claims 1, 4-6, 9 and 10 are pending in the application. Claims 1, 4-6, 9 and 10 are rejected.

Claims 1 and 6 are amended to delete the number of fragments. Support is found throughout the specification, for example, at page 5, first full paragraph.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 4, 6, and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent No. 4,096,138).

Claims 5 and 10 also are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Dosa et al. (Immunology, 1979, 38, pages 509-517) and further in view of Scherr (US Patent No. 4,096,138) as applied to claims 1, 4, 6, and 9 above, and further in view of Nakase et al. (JP 48019719 Abstract Only).

For the following reasons, the rejections are traversed and/or overcome.

(i) Summary

The Examiner stated in the Office Action that:

"Hunter et al. teach agglutination procedures to measure antibody-antigen binding. In one embodiment, pepsin treated antibodies are coupled to BSA (protease treated BSA) and use[d] to measure antigen interaction via agglutination....

Hunter et al. are silent with respect to the pepsin digest rendering fragmented BSA. However, Dosa et al. disclose the effect of peptic degradation on the immunological and antigenic properties of bovine serum albumin (BSA)....

Hunter et al. discloses the claimed invention except for the fragmented BSA produced from pepsin digestion.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to degrade BSA with pepsin thereby producing fragmented BSA because Dosa et al. taught that the systematic degradation of BSA with pepsin provided an excellent model for investigating the function and nature of different antigenic determinants present on protein antigens." (pages 3-4 of the Office Action)

That is, the Examiner admits that the use of the protease-treated fragmented BSA is not disclosed in Hunter et al., but concludes that those skilled in the art would have been motivated to substitute the protease-treated fragmented BSA for BSA in view of the teachings of Dosa et al. to attain the present invention.

Applicant disagrees. In order to establish a *prima facie* case of obviousness, the references must, in combination, teach each and every limitation of the currently claimed invention, *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974). Second, the Examiner must provide sufficient reasons why one of skill in the art would combine the references to arrive at the claimed invention. Finally, there must be a reasonable expectation of success in combining the references. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

In this respect, the reagent disclosed in Hunter et al. requires that BSA should be used in the form of undigested BSA to detect an analyte of interest (i.e., anti-BSA antibody), and

therefore, the use of the protease-treated fragmented BSA would not have been suggested from the teachings of Hunter et al. and Dosa et al., as described in below in (ii).

In addition, the Examiner mentioned that Dosa et al. discloses the immunological effect that digested BSA fragments did not form BSA-anti-BSA immune complexes. Applicant asserts that in view of this teaching, one of ordinary skill in the art would not have replaced BSA used in Hunter et al. with the protease-treated fragmented BSA, as described below in (iii).

(ii) Reagent disclosed in Hunter et al.

The reagent disclosed in Hunter et al. is schematically illustrated in Attachment A.

The reagents disclosed in Hunter et al. are used for measuring human reaginic antibodies (page 354, line 1), such as an anti-casein antibody (Fig. 1 on page 355) or an anti-BSA antibody. In an embodiment for measuring the anti-BSA antibody, pepsin-digested $F(ab)_2$ fragments of an anti-red cell antibody are chemically coupled to BSA (page 363, lines 27-28), and the resulting BSA-coupled antibody reagent is linked to red cells by an antigen-antibody reaction (Fig. 1) to obtain a reagent for measuring the anti-BSA antibody.

From this disclosure, it would be apparent to one of ordinary skill in the art that the BSA to be coupled to the pepsin-digested $F(ab)_2$ fragments of anti-red cell antibodies in this embodiment should be full length of BSA, in order to detect all types of anti-BSA antibody thoroughly. Therefore, the use of protease-treated fragmented BSA would not have been suggested from the teachings of Hunter et al. and Dosa et al.

In this regard, Applicants note that "[if a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed.Cir.1984). Thus, Applicants respectfully submit that one of ordinary skill in the art would

not have possessed *any* motivation to combine the teachings of Hunter et al. and Dosa et al., and hence the rejection is improper for at least this reason. Further, as a result of such lack of motivation, one of ordinary skill in the art would not have a reasonable expectation of success in combining the references, as is also required to maintain a finding of obviousness. Applicants respectfully submit that the claims are not obvious at least in view of the foregoing.

(iii) Effects disclosed in Dosa et al.

The Examiner further stated in the Office Action that:

"Hunter et al. are silent with respect to the pepsin digest rendering fragmented BSA. However, Dosa et al. disclose the effect of peptic degradation on the immunological and antigenic properties of bovine serum albumin (BSA). See abstract. BSA was digested with pepsin and the fluorescence-binding efficiency evaluated. The BSA fragments obtained from a digest did not form BSA-anti-BSA immune complexes (see page 511-512) and did not interact with B cells (see page 516, 1st column 1st paragraph)." (last paragraph on page 3)

As is apparent from the enclosed Attachment A, the immunological binding activity between X (such as BSA) and anti-X antibody (such as an anti-BSA antibody) is essential to detect the analyte (i.e., an anti-X antibody). However, those of ordinary skill in the art would know that Dosa et al. teach that the BSA fragments obtained from a digest did not form BSA-anti-BSA immune complexes. Thus, one of ordinary skill in that art would not have been motivated to substitute protease-treated fragmented BSA for BSA used in Hunter et al.

As pointed out above, "[if a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed.Cir.1984). Hence the rejection is improper for at least this reason. Further, as a result of

such lack of motivation, one of ordinary skill in the art would not have a reasonable expectation of success in combining the references, as is also required to maintain a finding of obviousness. Applicants respectfully submit that the claims are not obvious at least in view of the foregoing.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Susan J. Mack

Susan J. Mack
Registration No. 30,951

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: May 27, 2008